FREDERICK W. TILEY, M.D., IX.
Physician and Surgeon • Surgery for Spinal Disorders

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December 7, 1999

Document Management Branch(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

Dear Sir or Madam:

It has come to my attention that the FDA is suggesting that allograft be classified as a medical device. That is a totally ludicrous proposition. Allografts are tissues that are used on a routine basis going from one human being to another for treatment purposes. They are not medical devices. It would be as ludicrous to consider a blood transfusion from one individual to another as a medical device.

The decisions to use allograftic tissue are medical decisions done with due diligence with respect to all medical knowledge and there is no necessity for regulation of allografts as medical devices.

I have been appreciative of the FDA oversight of allograft providers with reference to safety and I would hope that would continue.

Sincerely,

Frederick W. Tiley, M. D.

FWT:g

97N-484S C124

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